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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/747,760	12/21/2000	Richard Glynne	18547-046600US	4702

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TOWNSEND AND TOWNSEND AND CREW LLP
TWO EMBARCADERO CENTER
8TH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
PONNALURI, PADMASHRI	
ART UNIT	**PAPER NUMBER**
1639	

DATE MAILED: 11/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/747,760	Applicant(s) Mack et al
	Examiner Padmashri Ponnaluri	Art Unit 1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Aug 26, 2002* .

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above, claim(s) *3-21* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1 and 2* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☒ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

NOTE: The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1639.

1. This application claims priority to provisional application 60/171,796 filed on 12/22/99.

2. Applicant's election with traverse of group I, claims 1-2, in Paper No. 7, is acknowledged. The traversal is on the ground(s) that groups I and groups II set forth stem from a common concept and theory, and are thus related. As such prosecution of the claims of groups I and II would not place a substantially greater burden on the examiner. This is not found persuasive because Group I inventions are drawn to a method in which a single gene expression profile and not more than one or a set of genes as in group II. The set of genes in group II include a specific set of genes (more than one) and require further search which differs from the group I invention search in which only a single specific gene expression is required. The reference anticipating Group I one would not render the others obvious absent ancillary art. Additionally, the Group II set of genes would require different and separately burdensome manual/computer bibliographic and classification searches in patent and literature databases; and have acquired a separate status in the art because of their recognized divergent subject matter, which makes restriction for examination purposes as indicated proper.

The requirement is still deemed proper and is therefore made FINAL.

3. Applicant's election without traverse of CD72 as species of gene, in Paper No. 9, filed on 8/26/02 is acknowledged

4. Claims 3-21 are withdrawn from further consideration pursuant to 37 CAR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7.

5. Claims 1-2 are currently being examined in this application.

6. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

7. Claims 1 is objected to because of the following informalities: claim 1 recites genes by the abbreviations, which are not common. Applicants are requested to provide either full name of the genes and/or common name of the genes. Appropriate correction is required.

8. The use of the trademark such i.e., LIPOFECTAM in page 55 has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Applicants are requested to check for other trade names listed in the specification and should capitalize them all.

9. The attempt to incorporate subject matter into this application by reference to PCT documents and provisioanl applications have been noted in the specification, which is improper because the subject matter which applicants request to incorporate by reference is essential for the current invention.

10. The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 U. S. P. Q. 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 U. S. P. Q. 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 U. S. P. Q. 167 (CCPA 1973).

11. The listing of references in the specification is not a proper information disclosure statement. 37 CAR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

12. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Foulkes et al (US Patent 5,580,722).

The instant claims briefly recite a method of screening drug candidates by adding a drug candidate to a cell that expresses expression profile gene, and determining the effect of the drug candidate on the expression of the expression profile of the gene.

Foulkes et al disclose a method to determine whether a molecule not previously known to be a modulator of protein biosynthesis is capable of directly and specifically transcriptionally modulating the expression of a gene encoding a protein of interest associated with treatment of one or more symptoms of a cardiovascular disease (i.e., see abstract). The reference discloses that the cardiovascular disease may be associated with thrombosis (i.e., see column 21). The reference discloses that the protein of interest may be CD36 (i.e., see column 21, line 66) (refers to one of expression profile gene of the instant claims). The reference discloses in claim 1, a method of determining whether a chemical not previously known to be modulator of protein biosynthesis (refers to drug candidate of the instant claims) is capable of modulating expression of a gene encoding a protein of interest, by contacting the sample which contains the predefined

eukaryotic cells consisting of gene encoding protein of interest (refers to the cell of the instant claims); quantitatively determining the amount of the signal so produced (refers to step c) of the instant claims); comparing the amount so determined with the amount of produced signal detected in the absence of any chemical being tested refers to instant claim 2). Thus the reference clearly anticipates the claimed invention.

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claims 1-2 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/10365 (LOCKHART et al) and Grosveld et al (US Patent 6,110,666) .

Lockhart et al teach methods of monitoring the expression levels of a multiplicity genes. The reference teaches a method of idnetifying genes that are effected by one or more dugs, or conversely screeing a number of drugs to identify those that have effect on particular genes (i.e., see page 8, lines 31-32 and the line bridging pages 8 and 9). The method provides a pool of target nucleic acids from one or more cells (refers to the instant clams steps a) and b)) contacted with the drug or drugs and hybridizing that pool to any of the high density oligonucleotide arrays. The reference teaches that the expression levels of the genes targeted by the probes in the array are determined and compared to expression levels of genes from control cells not exposed to the drug or drugs (refers to instant claim 2) (i.e., see page 9, lines 1-6). The genes that are overexpressed or underexpressed in response to the drugs are identified or conversely the drug or drugs that alter expression of one or more genes is identified (i.e., see page 9, lines 6-8).

The reference teaches that the genes of particular interest for expression monitoring include genes invovled in pathways associated with various pathological conditions (e.g., cancer) and whose expression is thus indicative of the pathological condition. Such genes include but are not limited to HER2 (c-erbB-2/neu), receptor protein kinases associated with etiologiy of number of tumors including carcinomas of breast, liver, bladder, pancreas as well as glioblastomas, sarcomas, squamous carcinomas, tumor suppressor genes such as p53 and other marker genes such as RAS, MSH2, MLH1, BRCA1. Other genes of particular interest for expression monitoring are genes involved in the immune responses, as well genes involved in cell adhesion and signal transduction, etc. (I.E., see page 8, lines 19-29).

The claimed invention differs from the prior art teachings by reciting specific cells that express specific genes (CD72 is the elected gene). Lockhart et al teaches a method of idnetifying genes that are effected by one or more dugs. The reference teaches that the genes of particular interest for expression monitoring include genes invovled in pathways associated with various pathological conditions, and genes involved in immune responses, cell adhesion and signal transduction. The reference does not teach cells that express CD72. However, Grosveld et al (US Patent 6,110,666) teaches pre-B cell possess CD72 as cellular marker gene (i.e., see column 8, lines 8-9). The reference teaches a composition for targeted gene delivery to a target cell composing immune cell surface antigen CD72 (i.e., see column 22, lines 65-66). The reference teaches monitoring the levels of transduction, gene expression and/or the presence or levels of normal encoded protein will assist in selecting and adjusting the dosage administered (i.e., see column 23, lines 34-36).

Thus it would have been obvious to one skilled in the art at the time the invention was made to use the cells that express CD72 gene taught by Grosveld et al in the drug screening methods, because Lockhart et al teach a method of idnetifying genes that are effected by one or more dugs, Lockhart et al teaches that the genes of particular interest for expression monitoring include genes invovled in pathways associated with various pathological conditions, gene s involved in immune response.

17. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Ponnaluri whose telephone number is (703) 305-3884. The examiner is on ***Increased Flex Schedule*** and can normally be reached on Monday to Friday from 7.00 AM to 3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

P. Ponnaluri
Patent Examiner
Technology Center 1600
Art Unit 1639
31 October 2002

PADMASHRI PONNALURI
PRIMARY EXAMINER

PADMASHRI PONNALURI
PRIMARY EXAMINER